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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/691,917

10/23/2003

Ruchika Singhal

1023-234US01

6514

28863 7590 12/28/2009
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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

12/28/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pairedocketing@ssiplaw.com

Office Action Summary	Application No. 10/691,917	Applicant(s) SINGHAL ET AL.	
	Examiner MICHAEL KAHRELIN	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-19,23-38 and 42-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-19,23-38 and 42-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20091123, 20090917, 20090701</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 5-19, 23-38, and 42-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner was unable to find support in the originally-filed application for the amended claim limitation of monitoring the therapy "while the output of the sensor was monitored." Although the portions of the disclosure cited by Applicant (e.g., par. 0035) appear to support defining an event (e.g., running) and monitoring therapy delivered by the device during the event and/or during the "learning mode," the Examiner was unable to find support for monitoring therapy while defining the event (i.e., monitoring the sensor). For instance, the patient could begin the "event" (e.g., running) or initiate the learning mode; then the "event" is defined based on monitoring the sensor; and *subsequently* the therapy is monitored by the device (as shown in Applicant's Figures 5 and 6). These figures lack, and the corresponding text is also deficient in describing, an embodiment wherein the "initially defining" step occurs while "monitoring therapy" (i.e., performed in parallel). Just because these two acts are disclosed as occurring during the "learning mode,"

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does not mean that one occurs "while" the other occurs because both could occur in the learning mode (or while the patient is running), but at different times. This appears to be an unsupported range of when the "monitoring therapy" and "monitoring the sensor" steps occur. Should these limitations be removed from the claims, the previous rejections of record will be applied.

Response to Arguments

3. Applicant's arguments filed 9/17/2009 have been fully considered but they are not persuasive. Applicant argued that nothing in the disclosure precludes overlap of monitoring of the therapy and monitoring the sensor; and that an artisan of ordinary skill would have recognized that Applicant was in possession of the claimed invention because both monitoring steps are disclosed as occurring while the system is in a learning mode, or while the patient is running. As a threshold matter, the written description requirement "is separate and distinct from the enablement requirement." See MPEP § 2163 (citing *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991)). The provision is considered satisfied if the disclosure describes the invention in such detail that an artisan of ordinary skill would recognize the inventor had possession of the claimed invention. See *Id.* In this case, it is respectfully submitted that Applicant's argument that nothing *precludes* overlapping monitoring of the therapy and sensor, and that these steps *could be* performed in parallel is misplaced. The disclosure need not merely render the claimed subject matter obvious to an artisan of ordinary skill, but must convey that this particular embodiment *was possessed* by the inventor. The rejection under section 112, paragraph 1 was not

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made for lacking enablement (i.e., an artisan of ordinary skill could not have made this embodiment), but under the separate written description requirement (i.e., Applicant's disclosure has not conveyed possession of the claimed embodiment).

4. The Examiner maintains that Applicant has failed show possession of this embodiment by Applicant's citation to a passage indicating that both steps occur during a learning mode or during running. Both steps occurring during the same mode is no more of an indication that the steps occur simultaneously than would an indication that each step occurs at some point during the life of the device, or during the period that the device is implanted in the patient. The only reference that the Examiner could locate in the originally-filed disclosure to the temporal relationship between the two monitoring steps is in Figures 5 and 6, where these steps are shown as being carried out in series, and not in parallel. Applicant argued that Examiner's reference to this disclosure (and the accompanying textual description) does not establish that these monitoring steps would/could only happen at different times. However, under the written description requirement, such a burden does not exist. The Examiner does not assert that this embodiment is not enabled or impossible; only that Applicant has not shown possession of this embodiment.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHRELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762